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REMARKS

The above-referenced application is a continuation of parent application 09/810,815. Claims 1 through 10 were submitted in the above-referenced continuation application. The claims have been amended within this preliminary amendment (1) to reflect the claimed subject matter of the parent application as of December 11, 2003 and (2) in response to the outstanding Office Action of September 15, 2003 in the parent application.

Accordingly, Claims 2 and 5 through 9 have been cancelled without prejudice or disclaimer to the filing of continuing applications thereon.

Claim 1 has been further amended to recite that in advantageous embodiments the nicotine taste of the compounds of the invention can be masked for at least 5 minutes. Support for this amendment can be found in the Application-as-filed, for example on Page 11, lines 1 through 15.

Claims 11 through 14 have been added to complete the record for examination and to highlight advantageous embodiments of the invention.

Claim 11 has been added to reflect the claims as pending on December 11, 2003.

Claim 12 is directed to advantageous embodiments that include nicotine and two different sweeteners in a molar ration of 1:2. Support for Claim 12 can be found in the Application-as-filed, for example on Page 6, lines 27 through 30.

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Claim 13 is directed to beneficial aspects of such embodiments in which one of the sweeteners is acesulfame and the other sweetener is saccharin or aspartame. Support for Claim 13 can be found in the Application-as-filed, for example on Page 8, lines 22 through 32 and Page 10, line 11 through Page 11, line 15.

Claim 14 is directed to beneficial aspects of such embodiments in which the other sweetener is aspartame. Support for Claim 14 can be found in the Application-as-filed, for example on Page 10, line 11 through Page 11, line 15.

Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

The Claimed Invention is Patentable
in Light of the Art of Record

Claims 1, 3, 4, 10 and 11 stood rejected in the parent application as being unpatentable over WO 99/04822 ("WO 822") in view of United States Patent No. 4,753,800 to Mozda ("Mozda").

It may be useful to consider the claimed invention before addressing the merits of the invention. The claims are directed to compounds of nicotine and a sweetener, as well as their physiologically acceptable salts or addition salts with a physiologically acceptable acid. The claimed compounds include nicotine and sweetener in a molar ratio of 1:2. The sweetener molecules can be identical or different. The claimed compounds are highly advantageous, masking the nicotine taste of the compound for at least 5 minutes.

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In advantageous embodiments, the claimed compounds are included within a solid or liquid preparation, in the form of a chewing gum, a chewing tablet or compressed composition, as recited in Claim 10.

In further advantageous embodiments, the compound includes acesulfame and a different sweetener, as recited in Claim 12. In beneficial aspects of such embodiments, the different sweetener can be saccharin or aspartame, as recited in Claim 13. In particularly beneficial aspects, the different sweetener is aspartame, as recited in Claim 14.

Owing to the continuous consumption of cigarettes, smokers are habituated to regularly taking nicotine. Unfortunately, smoking has been determined to be quite hazardous to health, for a number of reasons. A number of treatments for smoking addiction are available.

One common treatment of smoking addiction is the administration of nicotine by means other than smoking. Such administration is problematic. In contrast to the vast majority of drugs, which are quickly ingested, nicotine must be provided to the addict in a duration similar to that of smoking, e.g. for several minutes or more. Nicotine exhibits an unpleasant taste, however, making its extended administration difficult, at best.

Chewing gums containing nicotine are known in art. For example, chewing gums containing nicotine have been known since about 1975. However, even after almost thirty years of development, there remains a long felt need in the art for nicotine preparations that provide a prolonged sweetness.

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Quite unexpectedly, Applicants have determined that nicotine compounds that include sweetener in a molar ration of 1:2 can mask the nicotine taste within preparations for at least 5 minutes. The Office Action of September 15, 2003 within the parent application urges that additional sweetener would be expected to provide more sweetness, i.e. a more intense sweetness. Applicants respectfully submit that it is the prolonged sweetness of the claimed invention that is altogether surprising. In particular, it is altogether unexpected that increasing the sweetener to nicotine molar ratio to 2:1 would mask the taste of nicotine compounds for at least 30 times longer than products having a 1:1 sweetener to nicotine ratio. The unexpected nature of the prolonged sweetness of the claimed invention is discussed in greater detail in the accompanying declaration by the first named inventor, Dr. Burgard, attached as Exhibit I.

WO 822 does not teach or suggest products having the prolonged sweetness of the claimed invention. WO 822 is merely directed to 1:1 salts of a sweetener and an unpleasantly tasting pharmaceutical. The pharmaceutical can be chosen from a laundry list of drugs, including drotaverin, prenoxidiazine and selegiline. (Page 2, lines 23 - 27). Nicotine is noticeably absent from the laundry list. The pharmaceutical, which may be ingested as a syrup, suspension or tablet, appears to be intended for quick ingestion. (Page 9, line 24 - Page 10, line 15). WO 822 notes that disagreeable tastes are noted during drug administration if the pharmaceutical is chewed "accidentally," for example. (Page 1, lines 11 - 16).

WO 822 does not teach or suggest the claimed invention, considered either alone or in combination with the art of record. More particularly, WO 822 does not teach or suggest either nicotine

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or a 1:2 nicotine to sweetener ratio. WO 822 further does not teach or suggest compounds that mask the taste of nicotine for at least 5 minutes. In fact, WO 822 teaches away from such compounds by emphasizing quickly ingested compositions. Accordingly, WO 822 also teaches away from the chewing gum and chewing tablets recited in Claim 10.

Furthermore, as WO 822 does not teach or suggest a 1:2 molar ratio, it does not teach or suggest compounds of nicotine and two different sweeteners present in a molar ration of 1:2, as recited in Claim 12. And WO 822 most certainly does not teach or suggest such compounds in which one of the sweeteners is acesulfame and the other sweetener is saccharin or aspartame, as recited in Claim 13. Hence WO 822 does not teach or suggest compounds in which the other sweetener is aspartame, as recited in Claim 14.

Mozda does not cure the deficiencies within WO 822. Mozda is directed to an altogether different way of providing improved taste to medicines. Rather than incorporate sweeteners, Mozda incorporates the medicament into a melted edible wax, which is then mixed with magnesium aluminum silicate. (Col. 1, lines 47 - 51). It is Mozda's belief that the absorption of the hot wax-medicament solution into the magnesium aluminum silicate renders the medicament unavailable for organoleptic taste prior to passage into the digestive tract. (Col. 2, lines 11 - 15). Mozda provides an extensive laundry list of suitable medicaments, including analgesics, such as acetaminophen, and antiasmatics, such as dextromethorphan. (Col. 3, line 51 - Col. 4, line 15).

The Examiner is correct in that Mozda does disclose nicotine as a medicament. However, nicotine appears buried within an extensive list of a multitude of different categories of

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medicaments, as well as numerous specifically identified medicaments. Mozda does not explain why or under what circumstances one should choose any particular medicament over the other, with the exception that it does disclose the preferable use of particular antitussives, decongestants and expectorants, which are all obviously different from nicotine. (Col. 4, lines 28 - 24).

Accordingly, Mozda, considered either alone or in combination with the art, does not teach or suggest the claimed compounds of nicotine and a sweetener, and particularly not such compounds having a molar ratio of 1:2.

There would have been no motivation to have combined these references. Applicants respectfully submit that merely because the references can be combined is not enough, there must still be a suggestion. MPEP 2143.01 (section citing Mills). Applicants respectfully submit that the Office Action is indulging in impermissible hindsight by merely picking and choosing elements from the prior art while using the instant specification as the guide for that selection process.

WO 822 discloses compounds formed from a 1:1 ratio of pharmaceutical to sweetener. It does not mention either nicotine or 1:2 molar ratios to provide prolonged taste masking. The Office Action then attempts to use the secondary reference to supply claimed elements missing from the primary reference. However, Mozda is not generally directed to nicotine, nor does it teach or suggest 1:2 molar ratios to provide prolonged taste masking.

WO 822 does not even address the issue solved by the instant application, i.e. prolonged taste masking, because the pharmaceuticals of the primary reference are administered quickly.

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Accordingly, WO 822 can not suggest a solution to that problem. The invention resides in the selection of particular elements from a wide number of possibilities to solve a specific problem.

However, even if the references were combined (which Applicants submit should not be done), the claimed invention would not result. More particularly, the claimed compounds of nicotine and a sweetener having a molar ratio of 1:2 would not result.

As noted above, WO 822 does not teach or suggest nicotine. Mozda is not primarily directed to nicotine, and there would have been no motivation to have selected nicotine from the laundry list provided.

WO 822 is further directed to 1:1 ratio products, which are adequate for the disclosed quickly ingested pharmaceuticals. Consequently, there would have been no motivation for WO 822 to have increased the sweetener to pharmaceutical ratio. However, if for some reason one had looked to Mozda (which, again, Applicants did not) one would have used Mozda's magnesium aluminum silicate to mask any unpleasant taste, rather than increase the sweetener to pharmaceutical ratio.

The combination of references further does not teach or suggest compounds of nicotine and two different sweeteners present in a molar ratio of 1:2, as recited in Claim 12. Nor does the combination teach or suggest the advantageous embodiments recited in Claims 13 and 14.

Accordingly, Applicants respectfully submit that Claims 1, 3, 4 and 10 through 14 are patentable in light of the combination of WO 822 and Mozda.

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CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1, 3, 4, 10 and new Claims 11 through 14 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional fees are necessary to allow consideration of this paper, the fees are hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

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